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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,102	07/25/2003	Michael William Dunne	PC 23140A (121*399)	3522

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
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GROTON, CT 06340

EXAMINER	
MCINTOSH III, TRAVISS C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,102	DUNNE, MICHAEL WILLIAM	
	Examiner	Art Unit	
	Traviss C. McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9-19,21,27 and 148-179* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,9-19,21,27 and 148-169* is/are allowed.

6)☒ Claim(s) *170-179* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed February 3, 2005 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

The abstract has been amended.

Claims 1 and 21 have been amended.

Claims 148-179 have been added

Claims 2-8, 20, 22-26, and 28-147 have been canceled.

Remarks drawn to rejections of Office Action mailed May 4, 2004 include:

Abstract objection: which has been overcome by applicant's amendments and has been withdrawn.

Claim objections: which have been overcome by applicant's amendments and have been withdrawn.

112 1st paragraph rejections: which have been overcome by applicant's amendments and have been withdrawn.

112 2nd paragraph rejections: which have been overcome by applicant's amendments and have been withdrawn.

102(a) rejection over P/S/L Consulting Group: which has been overcome by applicants amending their dosage amounts.

102(a) rejection over Block et al.: which has been overcome by applicants amending their dosage amounts.

103(a) rejection: which has been overcome by applicants amending their dosage amounts.

An action on the merits of claims 1, 9-19, 21, 27, and 148-179 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 170-179 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 170-175 recite the limitation "wherein the respiratory infection is caused by..." in the 1st line of each claim. There is insufficient antecedent basis for this limitation in the claims, as the claim from which they each depend from, claim 156, is silent to respiratory tract infections and is drawn to treating acute otitis media infections. Canceling the claims or amending them to depend from claim 21 would be seen to obviate the instant rejection. It is noted that if applicants amend these claims to depend from claim 1, they would be duplicates of claims 150-155 respectively.

Claim 176 comprises the word azithromycin wherein the typeface used includes **bold** and *italics*, and it is unclear as to why this word is typed in bold and italics (i.e., " a single dose of ***azithromycin*** wherein the dose..."). Removing the bold and italics would be seen to obviate this rejection.

All claims which depend from an indefinite claim are also indefinite. ***Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).***

Claim Rejections - 35 USC § 102

The rejection of claims 1-2, 5-8, 20-23, 28, 30-31, 34-37, 48, 50-51, 54-57, 68, 70-71, 74-77, 128, 130-131, and 134-137 as being rejected under 35 U.S.C. 102(a) as being anticipated by P/S/L Consulting Group (Ref. AM of IDS) is withdrawn.

It is noted that applicants arguing that the PSL Consulting Group is not a valid reference under 35 U.S.C. 102(a) is not convincing. The PSL Consulting Group article is available as prior art under 35 U.S.C. 102(a). For a reference to be considered valid under 35 U.S.C. 102(a), the reference must have a publication date earlier in time than the effective filing date of the application, and must not be applicant's own work, both of which are met by the PSL article. Below is an excerpt from the MPEP regarding overcoming a 102(a) rejection found in 706.02(b):

> A rejection based on 35 U.S.C. 102(a) can be overcome by:
> (A) Persuasively arguing that the claims are patentably distinguishable from the prior art;
> (B) Amending the claims to patentably distinguish over the prior art;
> (C) Filing an affidavit or declaration under 37 CFR 1.131 showing prior invention, if the reference is not a U.S. patent or a U.S. patent application publication claiming the same patentable invention as defined in 37 CFR 1.601(n). See MPEP § 715 for information on the requirements of 37 CFR 1.131 affidavits. When the claims of the reference U.S. patent or U.S. patent application publication and the application are directed to the same invention or are obvious variants, an affidavit or declaration under 37 CFR 1.131 is not appropriate to overcome the rejection.
> (D) Filing an affidavit or declaration under 37 CFR 1.132 showing that the reference invention is not by "another." See MPEP § 715.01(a), § 715.01(c), and § 716.10;
> (E) Perfecting a claim to priority under 35 U.S.C. 119(a)-(d) as explained in reference to 35 U.S.C. 102(e) above;
> (F) Perfecting priority under 35 U.S.C. 119(e) or 120 as explained in reference to 35 U.S.C. 102(e) above.

The P/S/L article discloses a single-dose regimen as an option for children with acute otitis media comprising 30 mg/kg of azithromycin. Applicants have amended their independent

claims to read as: methods of treating bacterial respiratory infections with about 40 mg/kg of azithromycin or higher; methods of treating bacterial respiratory infections with 2g of azithromycin; methods of treating acute otitis media (AOM) with about 40 mg/kg or higher of azithromycin; and methods of treating AOM with about 1.5-4.5g azithromycin. As such, these ranges for the claimed methods of treatment are not taught by the PSL document.

The rejection of claims 1-2, 5-8, and 20-23 under 35 U.S.C. 102(a) as being anticipated by Block et al. (reference Al of IDS) is withdrawn for the same reasons as above.

Allowable Subject Matter

Claims 1, 9-19, 21, 27, and 148-169 are allowed. The prior art does not teach or fairly suggest treating AOM using a single dose of azithromycin of about 40 mg/kg body weight (or about 1.5-4.5 g). It is noted that the closest prior art is seen to be the PSL document and Block et al. (both of record) who both disclose methods of treating AOM using a single dose of 30 mg/kg. One of skill in the art would not be motivated to nor find it obvious to increase the art known amounts of 30 mg/kg by over 33% to thus obtain a dosage of about 40 mg/kg, as in applicant's claims. Moreover, one of ordinary skill in the are would not be motivated to nor find it obvious to treat a bacterial respiratory infection with a dose of about 40 mg/kg or greater (or single 2g dose) of azithromycin, wherein the closest prior art is seen to be Schonwald et al. (reference filed in IDS on 10/12/04) who teach treating atypical pneumonia syndrome (a bacterial respiratory infection) with a single 1.5g dose of azithromycin. One of skill in the art would not be motivated to nor find it obvious to increase the art known amounts of 1.5 g by over 33% to thus obtain a

dosage of 2g or about 40 mg/kg, as in applicant's claims. The range of "about 40 mg/kg or greater" is not seen to be obvious over the prior art's taught range of "30 mg/kg".

The art made of record and not relied upon is considered pertinent to applicant's disclosure. Law et al., "Single-Dose Azithromycin for Respiratory Tract Infections", The Annals of Pharmacotherapy, vol. 38, pp 433-439, March, 2004.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
April 29, 2005

James O. Wilson
Art Unit 1623
Supervisory Patent Examiner